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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,401	09/24/2004	Magnus Qvist	77147	5704

26288 7590 05/18/2006

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EXAMINER	
MONDESI, ROBERT B	
ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 05/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/509,401	QVIST, MAGNUS	
	Examiner	Art Unit	
	Robert B. Mondesi	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *April 03, 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-22* is/are pending in the application.

4a) Of the above claim(s) *18-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Notice to Comply*.

DETAILED ACTION

Applicants' election of Invention of Group I, **Claims 10-17**, in response to the restriction requirement mailed January 4, 2006 is acknowledged. Because applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Therefore the requirement is still deemed proper and is made FINAL.

Status of the claims

Claims 1-9 have been canceled. **Claims 10-22** are new and pending. **Claims 18-22** are presently withdrawn for pertaining to non-elected subject matter. **Claims 10-17** are presently under examination.

Priority

The current application filed on September 24, 2004 is a 371 of PCT/SE03/00492 filed on March 25, 2003, which in turn claims priority to provisional application 60/374,129 filed April 22, 2002 and foreign application, SWEDEN 0200924-9 filed on March 26, 2002. A certified copy of foreign document SWEDEN 0200924-9 has been provided.

Preliminary Amendment

The preliminary amendments filed September 24, 2004 and April 21, 2005 have been entered.

Information Disclosure Statement

The IDS filed September 24, 2004 has been received and is signed and considered, a copy of the PTO 1449 is attached to the following document.

Specification

The disclosure is objected to because of the following informalities:

This application contains sequence disclosures at page 5, lines 25-31 through page 6, lines 1-4 that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a((1) and (a)(2). However, this application fails to comply with one or more of the requirements of 37 C.F.R. § 1.821 through 1.825 for one or more of the reasons set forth on the attached form "Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequences And/Or Amino Acid Sequence Disclosures". Wherein attention is directed to paragraph(s) §1.82 (c) and (e). Although an examination of this application on the merits can proceed without prior compliance, compliance with the Sequence Rules is required for the response to this Office action to be complete.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10 and 17 are directed to a method of attaching two surfaces; however the stated end result of the method is not two attached surfaces but rather an adhesive composition that is undergoing curing. Applicants need to amend the claim in order to provide an end point that matches the intention of the method as stated in the preamble.

If the method of the invention is directed to attaching two surfaces than the stated end result of the method should include the statement that the two surfaces are attachment.

Claims 11-16 are dependent claims that do not over come the deficiencies of the independent claim that they depend therefrom.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 10-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 01/44401 (Cited in the IDS filed September 24, 2004) in view of Deming et al. United States Patent No. 6,506,577.

Claims 10-11 and 17 of the instant application are directed to a method of attaching to surfaces to each other comprising providing a bioadhesive composition comprising an aqueous solution of a bioadhesive polyphenolic protein, providing a preparation comprising periodate ions; mixing said bioadhesive composition and said preparation to form an adhesive composition comprising at least 0.465 mmol/g of periodate ions; applying said adhesive composition to at least on of the two surfaces; joining said two surfaces; and curing said adhesive composition wherein said bioadhesive polyphenolic protein comprises 30-300 amino acids consisting of tandemly linked peptide repeats comprising 3-15 amino acid residues wherein and at least 3% of

said 30-300 amino acids are DOPA. **Claims 12-13** are dependent claims that teach a periodate ion concentration of 1.9 mmol/g or 2.0 mmol/g. **Claim 14** is a dependent claim that states the concentration of the adhesive composition is in the range of 10-50 mg/ml. **Claims 16-17** are dependent claims that indicate that at least one of the two attached surfaces is a biological surface or a non-biological surface.

WO 01/44401 discloses a bioadhesive composition comprising a polyphenolic protein comprising about 30-300 amino acid residues essentially consisting of tandemly linked peptide units comprising 3-15 amino acid residues and wherein at least 5% and preferably 6-25% of the residues are DOPA (Page 4, lines 20-32 and page 5, lines 1-15), wherein the concentration of the polyphenolic protein in the said bioadhesive concentration is in the range of 10-50 mg/ml (Page 6, lines 31-32) and that can be used for attaching two surfaces. In examples 1-13, pages 7-17, it is demonstrated and discussed how the composition of the invention is used in a method of attaching two surfaces. For example on page 8, lines 4-11 of WO 01/44401, it is stated that a block of corneal tissue was thereby isolated and removed from the original site and mussel adhesive protein (MAP) was administered into the wound cavity and thereafter where the shortly before removed corneal tissue pieces repositioned into the cavity to test for the adhesion and reattachment mediated by the MAP glue.

WO 01/44401 also discloses the use of a non-enzymatic oxidizing agent such as periodate ions in the said bioadhesive composition, wherein periodate ions such as sodium periodate are used in a concentration of 2.0 mmol/g counted on the final composition (Page 7, lines 3-7).

WO 01/44401 also teaches that at least one of the surfaces to be attached is a biological surface (Page 8, lines 5-11).

WO 01/44401 does not teach that one of the surfaces to be attached is a non-biological surface.

Deming et al. teach that one of the surfaces to be attached is a non-biological surface.

Deming et al. teach that their invention relates to adhesive copolymers modeled on bioadhesive proteins secreted by marine organisms. These copolymers are compatible with the metabolism, growth and function of living tissues and/or cells *in vitro* or *in vivo* and, consequently, are suitable for use in a wide variety of biomedical applications (Column 1, lines 22-28) (The adhesive precursor proteins have been isolated and sequenced from a wide variety of organisms and are known to show certain characteristics. A partial list of these proteins is given in FIG. 1).

Deming et al. describe the synthesis of moisture-resistant adhesive polypeptides, conditions for their use, and example applications. Illustrative polypeptides containing the amino acid L-dihydroxyphenylalanine (L-DOPA) were prepared as copolymers with L-lysine, L-glutamic acid, L-serine, L-alanine to give water soluble copolymers. Aqueous solutions of these copolymers, when mixed with various oxidizing agents formed cross-linked networks which were found to form moisture-resistant adhesive bonds to a variety of substrates (including aluminum, iron, glass, wood, and plastics). The novel features of this system are that the adhesive components are water-based, the polymers show exceptional bonding capabilities

toward wet materials including biological tissues, and the copolymers can be readily prepared in large quantities (Column 3, lines 54-67 and column 4, lines 1-3).

Deming et al. teach further that in another embodiment of the invention, the characteristic that is optimized by controlling the reaction environment is adhesive strength. For example, the adhesive strength can be manipulated by controlling the type of oxidizing agent present in the reaction environment. In a more specific embodiment, the adhesive strength can be manipulated exposing a specific copolymer composition to $NaIO_4$ (Column 7, lines 55-65) ($NaIO_4$ is a periodate salt that produces periodate ions in solution, see specification of present application on page 6, lines 17-20).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a bioadhesive polyphenolic protein in combination with periodate ions as mentioned above in a method of attaching two surfaces wherein at least one of the surfaces to be attached is a biological or non-biological surface for the advantages a method that precisely controls the material aspects of the mentioned adhesive with respect to curing time and adhesive strength and allows for wider biomedical and related commercial usage as taught by WO 01/44401 and Deming et al., see Deming et al. at column 3, lines 11-22.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 10-11 and 14-17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over **claims 1 and 4-6** of copending application No. 10498793. An obvious type double patenting rejection is appropriate where the conflicting claims are not identical but an examined application is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claims(s). *See In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and In re Longi, 759 F 2.d 887, 225 USPQ 645 (Fed. Cir. 1985).* Although the conflicting claims are not identical, they are not patentably distinct from each other **claims 10-11 and 17** of the instant application are directed to a method of attaching two surfaces to each other comprising providing a bioadhesive composition comprising an aqueous solution of a bioadhesive polyphenolic protein, providing a preparation comprising periodate ions; mixing said bioadhesive

composition and said preparation to form an adhesive composition comprising at least 0.465 mmol/g of periodate ions; applying said adhesive composition to at least on of the two surfaces; joining said two surfaces; and curing said adhesive composition wherein said bioadhesive polyphenolic protein comprises 30-300 amino acids consisting of tandemly linked peptide repeats comprising 3-15 amino acid residues wherein and at least 3% of said 30-300 amino acids are DOPA. **Claim 1** of copending Application No. 10498793 is directed to a method for attaching two surfaces to each other comprising the steps of providing a bioadhesive composition consisting of an aqueous solution of a bioadhesive polyphenolic protein derived from a byssus-forming mussel, which protein comprises 30-300 amino acids and consists essentially of tandemly linked peptide repeats 3-15 amino acid residues, wherein at least 3% of the amino acid residues of said bioadhesive polyphenolic protein are DOPA, wherein the concentration of said composition is within range of 10-50 mg/ml; providing a strongly alkaline solution with a pH of 10 or more, mixing said composition and said alkaline solution and applying the mixture to at least one of the surfaces, joining the said surfaces and leaving the said surfaces for a sufficient time for curing to occur. **Claim 1** of copending Application No. 10498793 does not state that the composition comprises periodate ions or is mixed with periodate ions; however in Example 1 (Page 10, line 2 of the of specification of copending Application No. 10498793), Example 2 (Page 13, line 6 of the specification of copending Application No. 10498793), Tables 1-2 (Pages 11-12 of the specification of copending Application No. 10498793) it is stated that $NaIO_4$, a periodate ion, is used. Tables 1-2 also indicate that when $NaIO_4$ is used the adhesive strength of the

composition is still retained; therefore the result of the method of attaching two surfaces of copending Application No. 10498793, in accordance with the teachings of the specification, would lead to the same end result of the method of attaching two surfaces of the present application.

Claims 14-16 of the present application are equivalents of **claims 4-6** of copending Application No. 10498793.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B. Mondesi whose telephone number is 571-272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert B Mondesi
Patent Examiner
Group 1653

Robert B. Mondesi

05-11-06

Notice to Comply	Application No.	Applicant(s)	
	10/509,401	QVIST, MAGNUS	
	Examiner	Art Unit	
	Robert B. Mondesi	1653	

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☐ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☒ 7. Other: Sequence disclosures at page 5, lines 25-31 through page 6, lines 1-4 need to be designated by a SEQ ID NO:

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
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